Correspondence

Nationwide prediction of future expenditure for protease inhibitors in chronic hepatitis C

Dear Editor,

Peginterferon plus ribavirin is the current standard of care for chronic hepatitis C, which determines sustained virological response (SVR) in 30–50% of patients. Protease inhibitors (namely boceprevir and telaprevir) are a further advancement that could increase SVR to approximately 60% [1]. Boceprevir and telaprevir have already been approved by the Food and Drug Administration (FDA) and are about to be marketed in Europe (boceprevir is available in France where its cost per patient is around €22,000 according to the website http://viralmatters.blogspot.com). The globalization of pharmaceutical markets has much increased the international homogeneity of drug prices; hence, transferring the cost of innovative drugs from one country to another is likely to imply a reasonable approximation.

Predicting the economic impact of adding a protease inhibitor to patients treated for hepatitis C is a crucial point in terms of pharmaceutical governance, especially in countries like Italy where the national health system provides full economic coverage of all essential treatments. The first step in evaluating an innovative treatment is to determine its cost-effectiveness; if the pharmacoeconomic profile is acceptable and the drug is therefore likely to be used, the next step is to estimate the budget impact.

Since preliminary studies [2] indicate that the cost-effectiveness of these protease inhibitors is favourable, a budget impact analysis focused on these agents is worthwhile. The national expenditure for ribavirin in Italy has been €33 million in 2009; assuming that each patient receives 840 capsules for a whole treatment (considering a cost of €4.2 per capsule, and including adjustments for treatment interruptions and suboptimal compliance [3]), this figure of national expenditure indicates that 9300 Italian patients/year receive treatment for hepatitis C regardless of their genotype. Given that genotype 1 accounts for 60% of all patients [4], this translates into a prediction of 5500 Italian patients with genotype 1 to be treated yearly with a protease inhibitor.

To estimate the economic impact of adding a protease inhibitor to these patients, we used a prediction model described previously [5]. According to this model, the yearly expenditure for the drug is directly proportional to the yearly number of treated patients (where the proportionality factor is the yearly cost per patient). The model is not drug-specific because the mathematical function simply handles an initial phase where expenditure increases as more and more patients of the eligible yearly population are being treated over time.

Fig. 1 shows the results of our budget impact analysis for protease inhibitors based on this model. In our base-case prediction, after projecting the expenditure for up to 5500 patients/year from mid-2012 until 2017, the overall budget impact is estimated to be €115 million per year at steady state (solid line).

Two factors affect the above budget impact analysis by acting in opposite directions. The first is that the patients actually receiving treatment for hepatitis C (as estimated from ribavirin consumption) are only a small subgroup of the overall Italian population infected by the virus [4]; hence, our figure of 5500 patients treated every year can be underestimated. The second factor is that our base-case analysis could instead be an overestimate of the true value because the new agents could be selectively employed only in a subset of the potential population.

The two sensitivity analyses shown in Fig. 1 were aimed at testing this latter hypothesis. The assumption for these analyses was that the population actually treated is restricted to 67% (dashed line) or 33% (dotted line) of the target of 5500 patients; on the basis of this assumption, the budget impact is consequently reduced.

Conflict of interest

The WEF-E study group has been promoted and funded by a private company 3P-Solution (Milan, Italy) that has received unrestricted grants for this purpose. The group has adopted the ethical declaration posted at http://www.wel2011.it/contenuti.php?id=14; the same URL indicates the whole list of WEF-E members and the scientific societies that have endorsed this project. Members of this group received no honorarium for their activity.

Fig. 1. Time course of the predicted incremental expenditure for protease inhibitors in 5500 patients with genotype 1 (solid line). As a sensitivity analysis, this budget impact prediction is restricted 67% (dashed line) or 33% (dotted line) of the overall population. The equations used to estimate the incremental budget [5] are $PTS = TARGET \times (1 - e^{-0.005 \times HLGrowth \times t})$ where $PTS$ = patients being treated at time $t$; $TARGET$ = yearly population receiving the treatment; $HLGrowth$ = half-life of the process of drug uptake in the market, and $TARGET$ = yearly population receiving the treatment; $Holgrowth$ = half-life of the process of drug uptake in the market, and [nationwide yearly expenditure] = (cost per patient) $\times PTS$; $PTS_{mean}$. The parameters used for this simulation were: $TARGET$=5500 patients; $Holgrowth$=3 months; cost per patient = €21,000 per patient. The time at which the expenditure for protease inhibitors was started was set at 12 months after the date of manufacturer’s application at EMA (19 May 2011).

References


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